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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,256	04/08/2004	Robbert Benner	2183.03-6420US	1851
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TRASK BRITT				
P.O. BOX 2550				
SALT LAKE CITY, UT 84110				
EXAMINER				
KIM, YUNSOO				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
07/17/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary

Application No.

10/821,256

Applicant(s)

BENNER ET AL.

Examiner

YUNSOO KIM

Art Unit

1644

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 1/308, 4/1408
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 3-8 and 10-14 are pending and are under consideration.
2. The IDS filed on 1/3/08 and 4/14/08 have been acknowledged.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-8 and 10-14 stand rejected under 35 U.S.C. 103 as being unpatentable over 2004/0013661 (IDS reference, of record), as evidenced by Merck Index (17th ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550, of record) and Merriam Webster's Dictionary (p. 82, of record) in view of Dwinnell et al., (Atlas of Diseases of Kidney, Ch. 12, 1999 of record) and U.S. Pat. No., 5,273,961, or record, for the reasons set forth in the office action mailed 1/15/08.

Applicants' arguments filed on 4/14/08 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on the improper hindsight where the method of treating renal failure is from the specification of the instant application. Moreover, Applicants argued that the '961 patent does not teach treatment of acute renal failure, the '661 publication does not mention BUN.

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Applicants provided Prabhaker et al. and Xiao et al. references to point out inhibitory effect of urea in NO synthase.

Prabhaker et al. disclose the urea inhibits inducible nitric oxide synthase (iNOS) in activated macrophages and the urea accumulates in renal failure and measures severity of renal failure.

Xiao et al. disclose that the urea inhibits L-arginine transport which is reduced by the renal failure.

However, there are different isoforms of NOS (iNOS or eNOS) and different isoforms of enzyme involved in different mechanisms of NO involvement in renal injuries ('961 patent, col. 4-7). Xiao et al. teach that urea induced inhibition of L-arginine is not sufficient to inhibit eNOS activity (abstract). Therefore, other factors such as isoform involvement and mechanisms in renal injuries should be considered and the reference does not obviate the evidence of obviousness.

Both Prabhaker et al. and Xiao et al. teach urea is well known protein metabolite that accumulates in renal failure and conventionally to measure the severity of renal impairment (p. 1886 and p. 993, respectively). Therefore, lowering of the urea concentration is an indication of improvement of renal failure.

As discussed previously, the '661 publication teaches a method of treating ischemia reperfusion injury by administration of pharmaceutical composition comprising synthetic immunoregulator AQGV and the immunoregulator AQGV peptide is known to reduce production of NO ([0047], in particular).

The '961 patent teaches that the Acute Renal Failure is characterized as an ischemic injury (col. 7, lines 24-43) and Dwinnell et al. teach that the patients with acute renal failure has high blood urea nitrogen concentration (Fig. 12.1-4, in particular). The lowering of BUN by reducing NO is an expected property of the AQGV peptide in the treatment of acute renal failure or ischemic injury.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ administration of AQGV composition as taught by the '661 publication in a method for treating acute renal failure as taught by Dwinnell et al and the '961 patent.

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One of ordinary skill in the art would have been motivated to treat acute renal failure by administration AQGV peptide composition as taught by the '661 publication because the AQGV peptide is known to lower NO and the lowering the blood urea nitrogen concentration is an indication of treatment of acute renal failure as taught by Dwinnell and the '961 patent.

From the teachings of the references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Therefore, the combination of references remains obvious.

5. No claim is allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F, 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim

Patent Examiner

Technology Center 1600

July 10, 2008

/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644

Application Number**Application/Control No.**

10/821,256

**Applicant(s)/Patent under
Reexamination**

BENNER ET AL.

Examiner

YUNSOO KIM

Art Unit

1644